SECTION 5
510(k) SUMMARY

510(k) Notification K K111731

GENERAL INFORMATION

Applicant:

Gamma Medica-Ideas, Inc.
19355 Business Center Drive, Suite #8
Northridge, CA, 91324 U.S.A.
Phone: 818-709-2468
Fax: 818-709-2464

Contact Person:

Albert Boniske
Regulatory Consultant for Gamma Medica-Ideas, Inc.
755 N. Mathilda Avenue, Suite 100
Sunnyvale, CA 94085 U.S.A.
Phone: 408-400-0856 ext. 113
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Date Prepared: June 17, 2011

DEVICE INFORMATION

Trade Name:

Molecular Breast Imaging Software

Generic/Common Name:

Picture Archiving and Communications System

Classification:

21 CFR§892.2050

Product Code:

LLZ

PREDICATE DEVICE(S)

- HERMES HDAQ Acquisition Station and HERMES Workstation (K002782)
- Segami Mirage (Release 5.0) (K010726)
- Philips Medical Systems (Cleveland) NM Application Suite (K080961)

SECTION 5
510(k) SUMMARY (CONT.)

INTENDED USE

The Molecular Breast Imaging Software is designed to acquire nuclear medicine image data from the Gamma Medica-Ideas LumaGEM™ gamma camera systems. The Molecular Breast Imaging Software allows images and data to be stored, communicated, processed, analyzed, and displayed on a compatible workstation.

PRODUCT DESCRIPTION

The Gamma Medica-Ideas Molecular Breast Imaging Software ("MBI Software") is a software tool intended to display and process breast images captured with the Gamma Medica-Ideas LumaGEM™ gamma camera systems. The MBI Software contains functions of study display, Gray and Inverse Gray Images, Window/Level changes, Measuring Tool, image processing, and Save, Sum, and Reload (both raw and processed). Image processing is based on pixel-by-pixel analysis and algorithmic filters applications. The MBI Software application supports simultaneous display of multiple images, allowing the user to visualize several angles of the imaged breast tissue at once. The MBI Software is compatible with DICOM and other formats.

SUBSTANTIAL EQUIVALENCE

The proposed indications for use for the Molecular Breast Imaging Software are substantially equivalent to the indications for use for the predicate devices. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the Molecular Breast Imaging Software is substantially equivalent to the predicate devices.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary performance bench testing was conducted on the MBI Software to support a determination of substantial equivalence to the predicate devices. The MBI Software is based on a clinically validated software application, which was designed for breast tissue screening using gamma cameras. All necessary verification and validation testing was conducted to ensure that the MBI Software performs as intended. This testing included:

- Software verification and validation
- Direct comparison testing between the subject device and the original application

SUMMARY

The results of the software verification and validation testing and the direct comparison testing has demonstrated that the Molecular Breast Imaging Software performs as intended. As such, the Molecular Breast Imaging Software is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Gamma Medica-Ideas Incorporated
% Mr. Albert Boniske
Senior Manager of Regulatory Affairs
Experien Group LLC
755 N. Mathilda Avenue, Suite 100
SUNNYVALE CA 94085

SEP 15 2011

Re: K111731
Trade/Device Name: Molecular Breast Imaging Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 17, 2011
Received: June 20, 2011

Dear Mr. Boniske:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111731

Device Name: Molecular Breast Imaging Software

Indications for Use:

The Molecular Breast Imaging Software is designed to acquire nuclear medicine image data from the Gamma Medica-Ideas LumaGEM™ gamma camera systems. The Molecular Breast Imaging Software allows images and data to be stored, communicated, processed, analyzed and displayed on a compatible workstation.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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